

REMARKS

Claims 35-41 are pending in the application.

Claims 1-34 were previously cancelled and Claims 35-41 are cancelled.

New Claims 42-48 are added.

Support for new Claims 42, 44, and 46-48 (in part) is found in the specification, including in original Claim 4; page 2, at line 27, to page 3, at line 1; on page 3, at lines 4-8; and on page 7, at lines 18-30.

New Claims 43, 45, and 46-48 (in part) correspond to cancelled Claims 36, 38, and 39-41 (in part), respectively. Support for new Claims 43, 45, and 46-48 (in part) is found in the specification, including in original Claim 8; page 2, at line 27, to page 3, at line 1; on page 3, at lines 4-8; and on page 7, at lines 18-30.

Claim Rejections - 35 U.S.C. § 112, first paragraph

Claims 35-38 are rejected under 35 U.S.C. § 112, first paragraph, in the Office Action as allegedly “failing to comply with the written description requirement.” The Examiner alleged, “There does not appear to be any evidence disclosed in the specification of synergism between gabapentin and NMDA receptor antagonist. Nor is there a disclosure of the ratio of 1:50 to 50:1.”

Applicants respectfully traverse this rejection on the grounds that Claims 35-41 are cancelled and new Claims 43 and 45, which correspond to Claims 36 and 38, do not contain references to synergism or ratios. Applicants believe that new Claims 43 and 45 comply with the written description requirement and are thus patentable under 35 U.S.C. § 112, first paragraph.

Claim Rejections - 35 U.S.C. § 102

Claims 35-41 are rejected under 35 U.S.C. § 102(e) as allegedly “being anticipated by Caruso et al US 6,187,338 B1.” The Examiner alleged in the Office Action that in Caruso et al., Claim 2 shows a combination of gabapentin and an NMDA receptor

antagonist and Claim 8 clearly shows methods for treating pain. The Examiner further alleged in the Office Action that particular anticonvulsants in addition to gabapentin which include pregabalin are shown in column 2, lines 29-34, of Caruso et al. In the Advisory Action, the Examiner alleged that Caruso et al. shows a combination of gabapentin and dextromethorphan at ratios that fall within the range of ratios of Claims 35, 37, and 39-41.

For proper anticipation, all of the elements of the claimed invention must be found within the four corners of a single reference. Applicants respectfully traverse the rejection because Claims 35-41 are cancelled, new Claims 43, 45, and 46-48 (in part) do not contain gabapentin, and Applicants believe that Caruso et al. does not teach the pregabalin element of new Claims 43, 45, and 46-48 (in part).

Applicants believe that Caruso et al. does not disclose pregabalin directly or by incorporation by reference. Applicants do not find pregabalin mentioned in Caruso et al., and thus conclude that no direct mention of pregabalin is made in the reference.

Column 2, at lines 29-45, of Caruso et al. references anticonvulsants on pages 1075-1083 of Remington's Pharmaceutical Sciences (1985) and pages 436-462 of Goodman and Gilman's The [Pharmacological] Basis of Therapeutics (1990). Applicants provide with the enclosed Supplemental Information Disclosure Statement ("Supplemental IDS") a copy of pages 436-462 of the Goodman and Gilman reference, which they believe does not disclose pregabalin. Further to the best of Applicants' knowledge, Applicants believe that Remington's 1985 publication date predates what Applicants believe is the first public disclosure of pregabalin, namely WO 93/23383, published November 25, 1993 (previously cited to the USPTO in Applicants Supplemental IDS mailed December 18, 2003). For this reason and because there was no disclosure of pregabalin in the Goodman and Gilman reference even though it was published five years after (i.e., 1990) publication of the Remington's reference, Applicants believe that the Remington's reference also does not incorporate pregabalin by reference.

Accordingly, Applicants believe that Caruso et al. does not anticipate new Claims 43, 45, and 46-48 (in part), or for that matter new Claims 42, 44, and 46-48 (in the other part), and that new Claims 42-48 are patentable under 35 U.S.C. 102(e).

Supplemental Information Disclosure Statement

Applicants further make available to the Patent and Trademark Office a Supplemental Information Disclosure Statement on form PTO/SB/08B and copies of the art cited thereon.

Applicants respectfully request that the Examiner consider carefully the complete text of the cited reference(s) in connection with the examination of the above-identified application in accord with 37 CFR §1.104(a).

It is respectfully requested that all cited reference(s) considered by the Examiner be listed in the "References Cited" portion of any patent issuing from the instant application (MPEP § 1302.12).

Conclusion

In view of the cancellation of Claims 35-41, the addition of new Claims 42-48, and the above remarks, Applicants believe that the rejection of Claims 35-38 under 35 U.S.C. § 112, first paragraph, and the rejection of Claims 35-41 under 35 U.S.C. § 102(e) are overcome. Applicants respectfully request withdrawal of the rejections and consideration of new Claims 42-48.

The Commissioner is hereby authorized to charge any other fees that may be required, or credit any overpayment, to deposit account number 23-0455.

The undersigned would welcome a telephone call from the Office to discuss any matters.

Respectfully submitted,

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Enc.:

- Request for Continued Examination on Form PTO/SB/30
- Supplemental Information Disclosure Statement on Forms PTO/SB/08A (1 page) and PTO/SB/08B (1 page)
- Copy of cited art